510(k) Summary for Dimension Vista™ Protein 1 Calibrator and Control L, M and H, Dimension Vista™ Protein 2 Calibrator and Control L and H, Dimension Vista™ Protein 3 Calibrator and Control

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

JAN 23 2007

The assigned 510(k) number is: K063508

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Helen Lee
Tel: 302-631-8706
Fax: 302-631-6299

Preparation date: November 17, 2006

2. **Device Name:** Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control L, M, H
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L and H
Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control

Classification: Class II; Class I
Product Code: JIX; JJY
Panel: Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**

Dimension Vista™ Protein 1 Calibrator - K062055
Dimension Vista™ Protein 1 Control L, M, H - K062055

Dimension Vista™ Protein 2 Calibrator - K062035
Dimension Vista™ Protein 2 Control L, H - K062035

Dimension Vista™ Protein 3 Calibrator - K061990
Dimension Vista™ Protein 3 Control - K061990

4. Device Descriptions:

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing α1-acid glycoprotein, C3 complement, C4 complement, haptoglobin, immunoglobulin A, immunoglobulin G, immunoglobulin M and prealbumin.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are multi-analyte, liquid human serum based products containing α1- acid glycoprotein, C3 complement, C4 complement, haptoglobin, immunoglobulin A, immunoglobulin G, immunoglobulin M and prealbumin.

Dimension Vista™ Protein 2 Calibrator
Protein 2 Calibrator is a multi-analyte, liquid human serum based product containing antistreptolysin O, C-reactive protein, *Cardio*Phase® *high sensitivity* CRP and rheumatoid factors.

Dimension Vista™ Protein 2 Control L and H
Protein 2 Control L and H are multi-analyte, liquid human serum based products containing antistreptolysin O, C-reactive protein, and rheumatoid factors.

Dimension Vista™ Protein 3 Calibrator
Protein 3 Calibrator is a multi-analyte, lyophilized, polygeline based product, with human source urinary and serum proteins, containing α_1-microglobulin and microalbumin.

Dimension Vista™ Protein 3Control
Protein 3 Control is a multi-analyte, lyophilized, polygeline, rabbit based albumin product, with human source urinary and serum proteins, containing α_1-microglobulin and microalbumin.

5. Device Intended Uses:

Dimension Vista™ Protein 1 Calibrator
Protein Calibrator is an *in vitro* diagnostic product for the calibration of the α1- acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of α1- acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) on the Dimension Vista® System.

Dimension Vista™ Protein 2 Calibrator
Protein 2 Calibrator is an *in vitro* diagnostic product for the calibration of the antistreptolysin O (ASL), C-reactive protein (CRP), *Cardio*Phase® *high sensitivity* CRP (*hs*CRP) and rheumatoid factors (RF) methods on the Dimension Vista® System.

Dimension Vista™ Protein 2 Control L and H
Protein 2 Control L and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of antistreptolysin O (ASL), C-reactive protein (CRP) and rheumatoid factors (RF) on the Dimension Vista® System.

Dimension Vista™ Protein 3 Calibrator
Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the α_1-microglobulin (A1MIC) and microalbumin (MALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 3Control
Protein 3 Control is an assayed intralaboratory quality control for assessment of precision and analytical bias in determination of α1-microglobulin (A1MIC) and microalbumin (MALB) on the Dimension Vista® System.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control L, M and H (modified to include 1- acid glycoprotein and haptoglobin) are substantially equivalent in intended use to the Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control L, M and H (K062055).

The Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ Protein 2 Control L and H (modified to include antistreptolysin O) are substantially equivalent in intended use to the Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ Protein 2 Control L and H (K062035).

The Dimension Vista™ Protein 3 Calibrator and Dimension Vista™ Protein 3 Control (modified to include α_1-microglobulin) are substantially equivalent in intended use to the Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ Protein 2 Control L and H (K061990).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Helen M. Lee,
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714

JAN 23 2007

Re: k063508
Trade/Device Name: Dimension Vista™ Protein 1 Calibrator, Dimension Vista™ Protein 1 Control L, M, H, Dimension Vista™ Protein 2 Calibrator, Dimension Vista™ Protein 2 Control L and H, Dimension Vista™ Protein 3 Calibrator, Dimension Vista™ Protein 3 Control
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX, JJY
Dated: November 17, 2006
Received: November 20, 2006

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

K063508

Indications Statement

Device Name: **Dimension Vista™ Protein 1 Calibrator**
Dimension Vista™ Protein 1 Control L
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Indications for Use:

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is an *in vitro* diagnostic product for the calibration of the α1-acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 1 Control L, M and H
Protein 1 Control L, M and H are for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of α1- acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin (PREALB) on the Dimension Vista® System.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use_____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063508

Indications Statement

Device Name: **Dimension Vista™ Protein 2 Calibrator**
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

Indications for Use:

Dimension Vista™ Protein 2 Calibrator
Protein 2 Calibrator is an *in vitro* diagnostic product for the calibration of the antistreptolysin O (ASL), C-reactive protein (CRP), *Cardio*Phase® high sensitivity CRP (*hs*CRP), and rheumatoid factors (RF) methods on the Dimension Vista® System.

Dimension Vista™ Protein 2 Control L and H
Protein 1 Control L and H are for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of antistreptolysin O (ASL), C-reactive protein (CRP), and rheumatoid factors (RF) on the Dimension Vista® System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063508

K063508

Indications Statement

Device Name: **Dimension Vista™ Protein 3 Calibrator**
Dimension Vista™ Protein 3 Control

Indications for Use:

Dimension Vista™ Protein 3 Calibrator
Protein 3 Calibrator is an *in vitro* diagnostic product for the calibration of the α_1-microglobulin (A1MIC) and microalbumin (MALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 3 Control
Protein 3 Control is for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of α_1-microglobulin (A1MIC) and microalbumin (MALB) on the Dimension Vista® System.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use _____ (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Page 3 of 3

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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(510(k) K063504